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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,968	08/01/2003	William J. Carroll	000309-00024	2521
27557	7590	05/26/2004		
BLANK ROME LLP 600 NEW HAMPSHIRE AVENUE, N.W. WASHINGTON, DC 20037			EXAMINER LAYNO, CARL HERNANDZ	
			ART UNIT 3762	PAPER NUMBER
DATE MAILED: 05/26/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/631,968	Applicant(s) CARROLL ET AL.	
	Examiner <i>Carl H. Layno</i> Carl H. Layno 5/25/04	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 9-11 and 16-19 is/are allowed.  
6) ☒ Claim(s) 1,4-8,12 and 13 is/are rejected.  
7) ☒ Claim(s) 2,3,14 and 15 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 01 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgement is made of applicant's claim for a priority filing based upon the submission of U.S Provisional Application Serial No. 60/400,066, filed August 2, 2002.

### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "108" has been used to designate both "circuit 1" electrodes and "circuit 2" electrodes in Fig.1 and because the reference character "208" has been used to designate both "circuit 1" and "circuit 2" electrodes in Fig.2. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The Examiner suggests renumbering the electrodes associated with "circuit 2" as "208" in Fig.1 to correspond with applicants' description in the specification (p.7, lines 23-25). Likewise, one pair of electrodes in Fig.2 should be designated as "108".

Applicant's drawings are informal and are acceptable for examination purposes only.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1, 4, and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Carter et al '358.

The Carter et al '358 patent describes a stimulator for bone growth treatment/osteogenesis (col.16, lines 5-18) including circuits (Figs.5-10) for generating interferential electrical signals via two sets of electrode pads **96,98,100,102** (Fig.8) to the skin of a patient. Each electrode pair delivers alternating electrical currents having frequencies of at least 1 KHz (col.3, lines 7-12).

In regard to claim 4, the "beat" frequency is between 1 Hz and 250 Hz (col.3, lines 18-42).

In regard to claim 5, applicants' attention is directed to col.16, lines 5-18).

5. Claims 1, 4, 6-8, 12, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al '425.

The Johnson et al '425 patent describes an apparatus for interferential current treatment (Fig.1), whose four electrodes **20,22,24,26** may be applied to the skin above the applicant's ankle bones (Fig.1, p.2 paragraphs [0019-0020]) or on opposite sides of the patient's spinal cord (p.2, lines (paragraph [0018])) to cause an interferential effect. The electrodes' current signals are generated by a digital signal processor **108** within the stimulator **10** (see Fig.4). The base frequency of the treatment electrodes is initially 1850 Hz (paragraph [0040]) but may be adjusted by the user.

In regard to claims 4, 8, and 15, the frequency of the first signal channel 12 is 1850 Hz, whereas the frequency of the second signal channel is within 200 Hz of that (i.e. 1650 Hz to 2050 Hz). This difference, or "beat" frequency cannot be any larger than 200 Hz.

In regard to claim 12, applicant's attention is directed to Figure 3, which appears to show pairs of electrodes **12,14,16,18** placed diagonally across portions L5 and S1 of the patient's body.

In regard to claim 13, these electrodes may be located at other selected extremities of the patient's body (i.e. shoulders, hand, foot, or leg). See paragraph [0025].

*Allowable Subject Matter*

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6. Claims 2, 3, 14, and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 9-11 and 16-19 are allowed.

8. The following is a statement of reasons for the indication of allowable subject matter:

Independent claims 9 and 16 recite apparatus and corresponding method claims describing an electrical bone stimulator for osteogenesis including the use of a field-programmable gate array (FPGA) for helping to generate sine-wave current treatment signals. None of the prior art references of record teach the use of this device in applicant's claimed manner except for the McGraw et al '487 patent. This reference, though cited herein, could not be used as prior art in view of its common inventorship and defective patent date. As a result, the Examiner deems independent claims 9 and 16, and their depending claims to be allowable over the prior art of record.

9. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

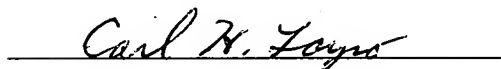
***Conclusion***

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message ([carl.layno@uspto.gov](mailto:carl.layno@uspto.gov)) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All faxed communications should be sent to the Office's new official FAX number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.

A handwritten signature in cursive script, reading "Carl H. Layno", is written over a horizontal line.

CARL LAYNO  
PRIMARY EXAMINER

CHL  
5/25/2004